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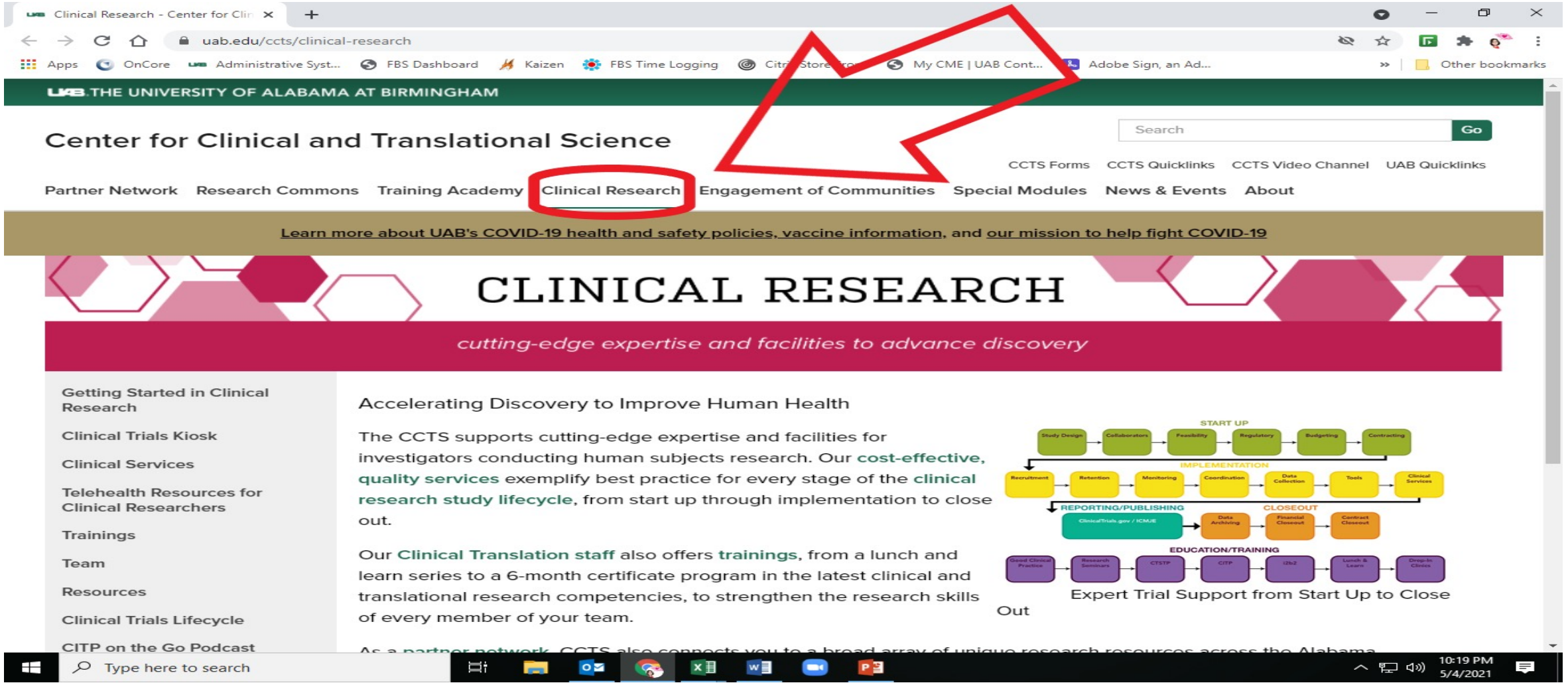
Zoom Etiquette

- Everyone will be muted.
- To ask a question, please use the Zoom chat box.
- Questions will be answered **after** the last speaker as time permits.
- In chat box, please include question, your name and email address.
- If your question is not answered, you will be emailed an answer by one of our speakers after the workshop.
- We appreciate your patience and cooperation.
- Slides, resources, and recording of session will be placed on the CCTS Clinical Trials Kiosk under the Budget Tools.

https://www.uab.edu/ccts/clinical-research/clinical-trials-kiosk



Getting Started in Clinical Research

Clinical Trials Kiosk

Clinical Services

Telehealth Resources for Clinical Researchers

Trainings

OnCore

Team

Resources

Clinical Trials Lifecycle

CITP on the Go Podcast

Contact

Meredith Fitz-Gerald, MSN, RN

Director, Clinical Research Support Program

WELCOME TO THE CLINICAL TRIALS KIOSK:

EVERYTHING YOU NEED FOR CLINICAL TRIALS RESEARCH

- UAB Research Administration Offices
- COVID-19 Support Documents & Resources
- Resources for Conducting Clinical Research
- Source Documents, Tools & Templates
- Investigator Toolkit
- Recruitment & Retention
- Study Coordinator T[illegible]tarter Kit
- Budget Toolkit
- Corrective Action and Preventative Plan (CAPA)

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Clinical Research Budget Workshop

Session One: Feasibility, Recruitment and Retention- A Team Approach

Meredith B. Fitz-Gerald, RN, MSN
Certificate in Clinical Research Management
Director of the CCTS Clinical Research Support Program (CRSP)
The University of Alabama at Birmingham (UAB)

Dana Rizk, MD
Professor of Medicine, Nephrology Division
Director of Clinical Trials Research
Medical Director of Clinical Trials Administrative Office
The University of Alabama at Birmingham (UAB)

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Objectives:

- Demonstrate use of Feasibility Worksheet and importance of assessment
- Enhance knowledge of team approach – Promote collaboration of entire Research team- PI, Coordinators, Regulatory, Finance, Data Management
- Promote use and stress importance of having a Recruitment and Retention plan.

Feasibility Analysis or Assessment (FA)

What is a FA?

- Process of evaluating the possibility of conducting a clinical study.

Why is a FA important?

- Investment of time, ensures you are choosing the right fit for your program.
- Identifies potential challenges.

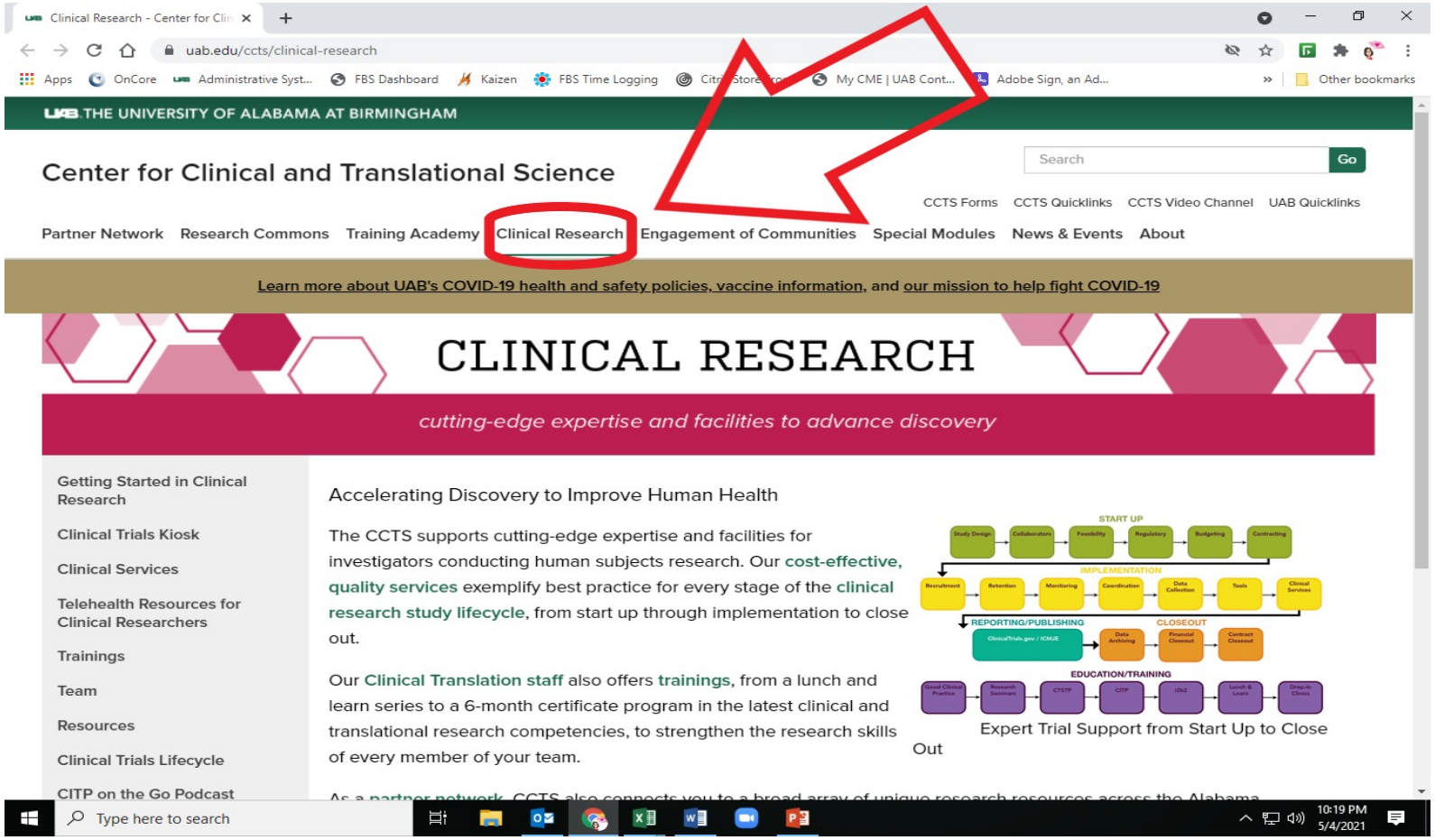
Overall objective = optimal project completion

Feasibility Checklist /Analysis Tool

- It is completed by study team and PI after review of protocol, consent form, draft budget and other related study materials.
- It is your best estimate of resources.
- It documents your desire and capability to participate in compliance with protocol requirements.

https://www.uab.edu/ccts/images/UAB_Protocol_Feasibility_Form_2021.pdf

https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk



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Current Covid Health and Safety Guidelines

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205-975-2758

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- Budget Toolkit
- Corrective Action and Preventative Plan (CAPA)
- Standard Operating Procedures (SOPs) Templates

Sample Feasibility Assessment Tool Key Sections

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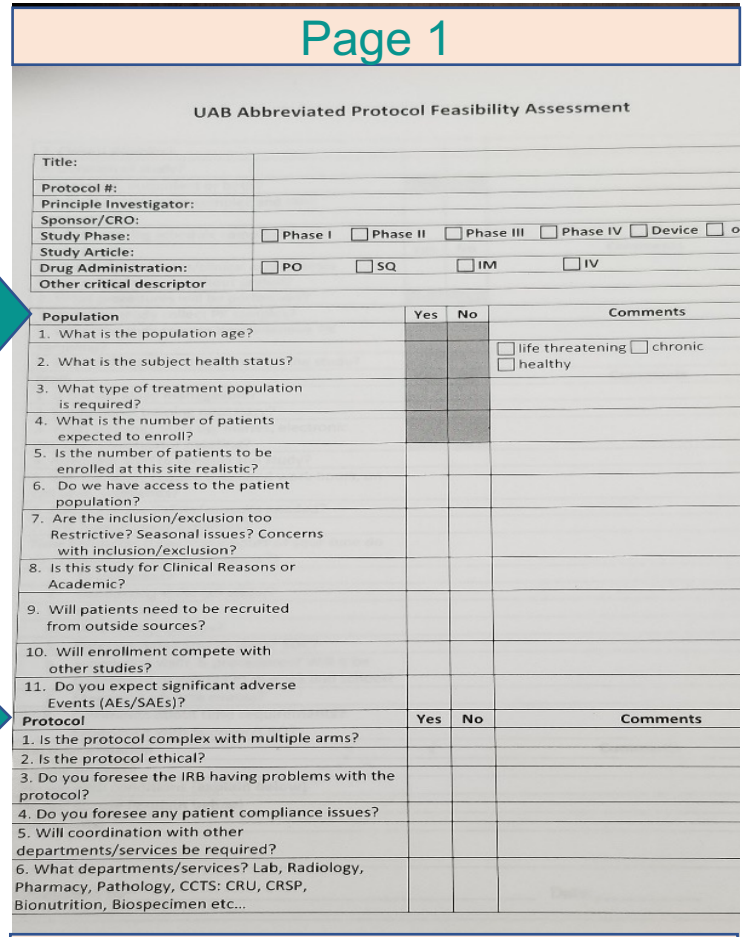


UAB Abbreviated Protocol Feasibility Assessment

Title:	
Protocol #:	
Principle Investigator:	
Sponsor/CRO:	
Study Phase:	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Device ☐ o
Study Article:	
Drug Administration:	☐ PO ☐ SQ ☐ IM ☐ IV
Other critical descriptor	

Population	Yes	No	Comments
1. What is the population age?			
2. What is the subject health status?			☐ life threatening ☐ chronic ☐ healthy
3. What type of treatment population is required?			
4. What is the number of patients expected to enroll?			
5. Is the number of patients to be enrolled at this site realistic?			
6. Do we have access to the patient population?			
7. Are the inclusion/exclusion too Restrictive? Seasonal issues? Concerns with inclusion/exclusion?			
8. Is this study for Clinical Reasons or Academic?			
9. Will patients need to be recruited from outside sources?			
10. Will enrollment compete with other studies?			
11. Do you expect significant adverse Events (AEs/SAEs)?			

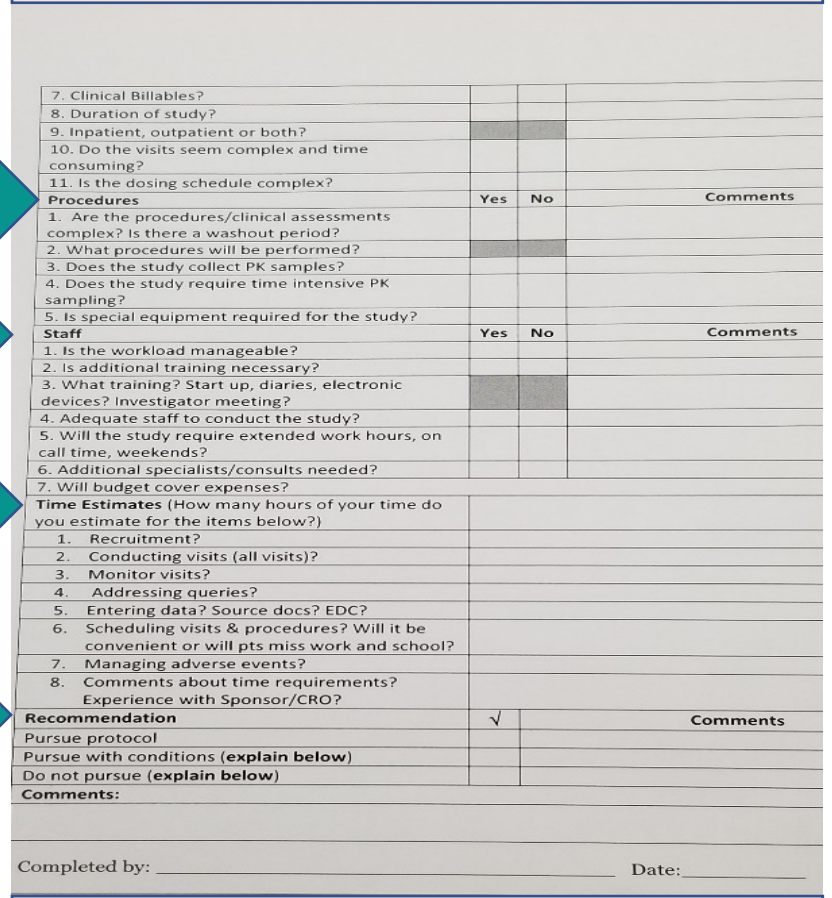
Protocol	Yes	No	Comments
1. Is the protocol complex with multiple arms?			
2. Is the protocol ethical?			
3. Do you foresee the IRB having problems with the protocol?			
4. Do you foresee any patient compliance issues?			
5. Will coordination with other departments/services be required?			
6. What departments/services? Lab, Radiology, Pharmacy, Pathology, CCTS: CRU, CRSP, Bionutrition, Biospecimen etc...			

Population

Protocol

Make it your own assessment:
Add Department/clinical area specifics

Page 2



Procedures	Yes	No	Comments
7. Clinical Billables?			
8. Duration of study?			
9. Inpatient, outpatient or both?			
10. Do the visits seem complex and time consuming?			
11. Is the dosing schedule complex?			
1. Are the procedures/clinical assessments complex? Is there a washout period?			
2. What procedures will be performed?			
3. Does the study collect PK samples?			
4. Does the study require time intensive PK sampling?			
5. Is special equipment required for the study?			

Staff	Yes	No	Comments
1. Is the workload manageable?			
2. Is additional training necessary?			
3. What training? Start up, diaries, electronic devices? Investigator meeting?			
4. Adequate staff to conduct the study?			
5. Will the study require extended work hours, on call time, weekends?			
6. Additional specialists/consults needed?			
7. Will budget cover expenses?			

Time Estimates (How many hours of your time do you estimate for the items below?)
1. Recruitment?
2. Conducting visits (all visits)?
3. Monitor visits?
4. Addressing queries?
5. Entering data? Source docs? EDC?
6. Scheduling visits & procedures? Will it be convenient or will pts miss work and school?
7. Managing adverse events?
8. Comments about time requirements? Experience with Sponsor/CRO?

Recommendation	√	Comments
Pursue protocol		
Pursue with conditions (**explain below**)		
Do not pursue (**explain below**)		
Comments:		

Completed by: _____ Date: _____

Procedures

Staff

Time Estimates

Recommendations

Add Department signoffs or reviewers
Use Comment areas to make notes or ask questions to sponsor.

Other Examples of Feasibility Tools

UAB Abbreviated Protocol Feasibility Assessment Form

Header

Protocol Title: _____
Protocol Number: _____
PI: _____

Protocol Phase: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Device

☐Other _____
Sponsor/CRO: _____
Protocol Article: _____

Drug Administration: ☐ N/A ☐ PO ☐ SQ ☐ IM ☐IV
Other Critical Descriptor: _____

POPULATION:

1. What is the population age? _____
2. What is the participant health status? ☐ life threatening ☐chronic ☐ healthy
3. What type of treatment population is required? _____
4. What is the number of participants expected to enroll? _____
5. Is the number of participants to be enrolled at this site realistic? ☐Yes ☐ No

Also remember to use a Recruitment and Retention Plan. A great team will have a well thought out plan of action **BEFORE** they start a study on how they are going to recruit participants and include this time and effort in their clinical trial budget.

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Clinical Research Support Program (CRSP)

UAB Recruitment/Retention Plan Worksheet

Protocol Title: _____
Protocol Number: _____
PI: _____
Protocol Synopsis: _____
Sponsor/CRO: _____

As part of the pre-study activities for the upcoming protocol, please provide the following information regarding your access to the required population and your site's initial plan for recruiting participants in this trial.

1. Based upon review/search of available databases, document the number of participants who fit protocol criteria and would be contacted for participation in trial: _____

On what sources are you basing this number?

- ☐ Medical Record Chart Review (i2b2, ICD-10 code search)
- ☐ Community Database
- ☐ Research Database
- ☐ Other: _____

2. Please list the potential challenges you see to enrolling participants and what you would implement to overcome these issues: _____

- ☐ Inclusion /Exclusion criteria too strict
- ☐ Distance/ Participant lives too far away/Participant Travel or Transportation Issues/Participant does not want to drive to UAB due to traffic/Parking
- ☐ Protocol requires too much from participant: procedures/frequency of visits/ duration of protocol (lasts for years)
- ☐ Study/Protocol will not pay participant for time to participate
- ☐ Age of participant population
- ☐ Investigational Product (IP) administration route/ requirements (multiple doses, injections, refrigeration)
- ☐ Randomization deterrent
- ☐ Seasonal illness/ Time of year for enrollment

Feasibility Checklist Components

Validating Enrollment Potential/ Patient Population:

- Do you have the potential subject population? Expected number to enroll? Be conservative!
- Is the inclusion/exclusion criteria realistic?
- Does the study require too much of the subject?
  - ❖ Time?
  - ❖ Cost?
- Are there extenuating circumstances that would adversely affect recruitment?
- What is the expected screen failure ratio?
- Will sponsor pay for unlimited screen fails?
- Do you have competing protocols in your department?
- Are vulnerable populations involved?

Feasibility Checklist Components

Protocol Considerations:

- Do you have previous experience with the sponsor or Contract Research Organization (CRO)?
- Do you have experience in the therapeutic area under investigation?
- Are procedures consistent with standard of care? Are they realistic?
- Is the study safe, ethical and scientifically sound?
- Is the study drug dosing complex?
- Is the protocol complex, multiple arms? Duration of Study?
- Are the follow-up visits reasonable? Any clinical billables? Multiple departments?
  - ❖ Are the visit windows acceptable/and or flexible enough? Any compliance issues?
  - ❖ Do visits need to be conducted on certain days to ensure best use of protocol windows?

Feasibility Checklist Components

Budget Considerations/Procedure Costs:

- Sponsor draft budget adequate? Is payment schedule reasonable?
- Will the sponsor pay for recruitment expenses?
- Does the budget include costs for administrative start-up? University required Fees?
  - ❖ IRB: drafting consent form, preparing IRB submission, Regulatory Paperwork
  - ❖ Contract: preparation and execution
  - ❖ Feasibility/Scientific Review
- Will the sponsor pay the required overhead?
- Will the sponsor pay for untimed items/events/labs/PKs as they occur? Procedures? Special equipment/training needed?
- Will the sponsor pay for document archiving, study closure, invoiceables?

Feasibility Checklist Components

Staff Requirements:

- Dissect protocol using the schedule of events schematic.
  - ❖ Evaluate all tasks involved. Are after/extended hours required?
  - ❖ Feasible with current staff workload? Will budget cover effort?
- Do you have qualified and dedicated staff to coordinate the trial?
- Will staff need to be trained?
- Request and review Case Report Forms (CRFs), questionnaires to assess time commitment, lab manual to process specimens, anticipate SAEs.
- Does the PI have adequate time and scheduling availability to devote to overall supervision of the trial?
- How often will the monitor visit?
- Do you need ancillary or specialty staff (pharmacy, labs, diagnostics, etc.)?

Feasibility Checklist Components

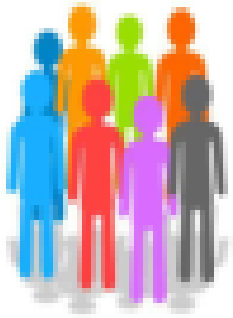
Facilities & Supplies:

- Is adequate clinical and office space available? Do you have storage space for supplies?
- Is special equipment required?
- Is access to emergency rescue equipment required?
- What will the sponsor supply?
  - ❖ Case Report Forms (CRFs)
  - ❖ Source documents
  - ❖ Electronic consent template
  - ❖ Packaged lab kits
  - ❖ Pre-paid shipping
  - ❖ Binders

COVID-19 Considerations:

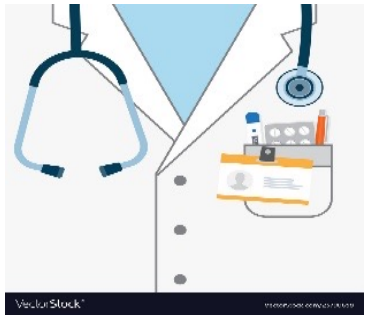
- Telemedicine Visits
- Remote follow up visits for patients
- Extra time for staff to arrange remote follow up visits and verbal consents
- Labs and procedural tests off site
- Budget/Protocol/Consent Amendments
- Management of results
- Investigational Product (IP) shipping
- Remote Monitoring

In Summary:



Subjects

- Is population available?
- Compliance issues?
- Vulnerable population?
- Requires too much time and Money?



Personnel

- Do you have staff?
- Do you have qualified staff?
- Is sponsor specific training required?
- Are staff needed after hours/ weekends?

Budget

- Per patient cost adequate?
- $$ for unplanned items?
- Will sponsor pay for archiving?
- Is payment schedule reasonable?

Facilities/Supplies

- Where will procedures be performed??
- Who will perform the procedures?
- Do you have the equipment and space?
- What supplies is sponsor providing?

Conclusion:

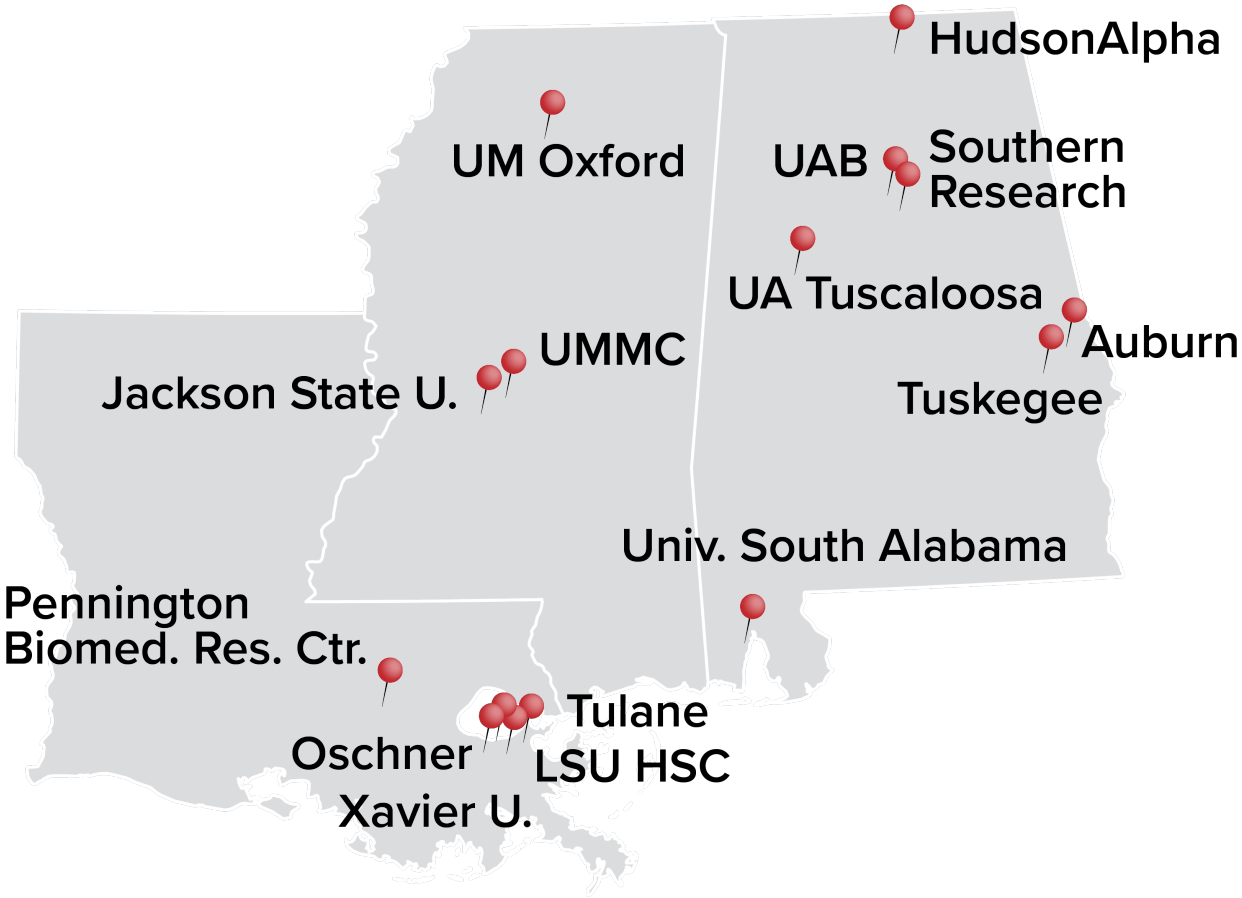
PLEASE consider ALL the components of a Feasibility Assessment (FA) before starting a trial and remember Recruitment /Retention of the participants is vital to the success of your clinical trial and budget. At the end of a clinical trial is important to analyze what went right/ wrong and did you cover your costs.

For Questions :

Please feel free to reach out to us!

CRSPtraining@uabmc.edu
mfitzgerald@uabmc.edu
afhenson@uabmc.edu

Questions?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Thank you for joining!